UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/408,023	09/29/1999	HARASH KUMAR NARANG	0769.00125	3494

22434 7590 04/26/2002

BEYER WEAVER & THOMAS LLP
P.O. BOX 778
BERKELEY, CA 94704-0778

EXAMINER	
ZEMAN, ROBERT	
ART UNIT	**PAPER NUMBER**
1645	17

DATE MAILED: 04/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/408,023	Applicant(s) NARANG, HARASH KUMAR	
	Examiner Robert A Zeman	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 March 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *see attached*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-3,5-9,11-13,15-17,19-21,24-29 and 44-47*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

ADVISORY ACTION

The amendment filed 3-19-2002 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search. Specifically the scope of the proposed amended claim 47 has changed since pending claim 47 does not claim amplifying DNA by both PCR and RFL methodologies. Additionally, claims 46 and 47 are substantial duplicates. Additionally, the amended claims raise new issues under 35 U.S.C. 112, second paragraph.

Objections Maintained

Specification

The objection to the use of the trademark Tween is maintained for reasons of record.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-14 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons of record.

Applicant argues:

1. Two types of buffers, blocking and washing, are used in the claimed invention.

2. The specification provides both a functional definition and specific examples of suitable blocking buffers.

3. A practitioner could readily test a variety of commercially available buffers to identify which one would be optimal for the particular system being used.

4. With regard to the granular calcium, it would not be an undue burden for one of skill in the art to identify the quantity or purity of calcium phosphate that is most suitable for use in the claimed invention.

Applicant's argument has been fully considered and deemed non-persuasive. As stated by Applicant pointed out on page 5 of the amendment, it is "unpredictable whether one specific buffer would be effective in removing impurities while still allowing the protein to remain complexed to the calcium granulars". Consequently, a practitioner could not readily identify which buffer would be optimal for a given system.

The rejection of claims 31-43 under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.for reasons of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 44-47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

As outlined in the previous Office action regarding claims 44-47, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

It should be noted that if the proposed amendment had been entered the aforementioned rejection would have been overcome.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-21, 24-33 and 37-43 under 35 U.S.C. 103(a) as being unpatentable over Schenk et al. (U.S. Patent 5,593,846), in view of Alaska et al. (U.S. Patent 5,744,587) and Chu et al. (U.S. Patent 4,604,208) is maintained for reasons of record as the amendment was not entered.

Applicant argues that the use of granular calcium phosphate overcomes some of the difficulties found in the use of hydroxyapatite and hence its use would not have been obvious from the prior art.

Applicant's arguments have been considered and have been found to be unpersuasive. Applicant asserts that granular calcium phosphate is superior since its use is not plagued by the same difficulties as the use of hydroxyapatite. Specifically, slow flow rate and the binding of more abundant contaminant proteins. Applicant's attention is drawn to page 8 of the specification that states "the method according to the present invention overcomes some of these difficulties by use of a medium that discriminates adsorption of albumin (in other words, proteins such as albumin are selectively not complexed as the medium **is caused to lose the charge** that allows albumin to complex). Hence, it is the non-disclosed **suitable buffer** that confers the selective binding not the granular calcium phosphate. Consequently, hydroxyapatite and granular calcium phosphate are equivalents with regard to the instant invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
April 23, 2002